

**REMARKS**

Pursuant to and consistent with 37 C.F.R. § 1.111, entry of the foregoing amendments and consideration of the following remarks is respectfully requested.

**Status**

Prior to the foregoing amendments, and as is correctly reflected in the Office Action mailed February 3, 2009 (“the Office Action”), Claims 28-46 are pending. *Office Action, Office Action Summary, Item 4.* Claims 28-46 stand rejected. *Id. at Item 6.*

**Summary of Amendments**

By the foregoing amendments, Applicants have amended the Specification to reflect that the instant application is a national phase application pursuant to 35 U.S.C. § 371 of and claims priority to International Patent Application PCT/CH2005/000092, filed on February 18, 2005, published as WO 2005/080395 on September 1, 2005, which claims priority to Swiss patent application number 285/04, filed on February 20, 2004, and that the contents of those applications are incorporated into the instant application in their entireties for all purposes. This amendment is clerical in nature. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claims 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, and 43 were amended to correct minor, typographic, and/or linguistic issues. Support for these amendments may be found throughout the Specification, and at least at prior claims 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, and 43, respectively. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claim 47 has been added. Support for new Claim 47 may be found throughout the Specification, and at least at prior Claim 28. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claims 44, 45, and 46 were cancelled without prejudice or disclaimer to Applicants filing one or more continuing applications directed to the previously-presented subject matter.

Further by the foregoing amendments, Claim 48 has been added. Support for new Claim 48 may be found throughout the Specification, and at least at prior Claim 32. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claim 49 has been added. Support for new Claim 49 may be found throughout the Specification, and at least at prior Claim 34. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claims 50 and 51 have been added. Support for new Claims 50 and 51 may be found throughout the Specification, and at least at prior Claim 39. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claims 52 and 53 have been added. Support for new Claims 52 and 53 may be found throughout the Specification, and at least at prior Claim 40. Accordingly, no new matter has been added.

Further by the foregoing amendments, Claim 54 has been added. Support for new Claim 54 may be found throughout the Specification, and at least at prior Claim 42. Accordingly, no new matter has been added.

Finally by the foregoing amendments, Claims 55, 56, and 57 have been added. Support for new Claims 55, 56, and 57 may be found throughout the Specification, and at least at Page 6, Lines 13-21 of the Specification. Accordingly, no new matter has been added.

### **Election/Restriction**

Applicants elected the claims of Group V (*i.e.*, Claims 13, and 18-27), with traverse, for prosecution in their Response filed December 1, 2008. The Examiner has acknowledged the election, as well as Applicants' subsequent cancellation of Claims 1-27. *Office Action, Page 2.* The Examiner notes that new Claims 28-46 read on the elected subject matter of Group V. *Id. at Page 3.* The Examiner has now made the restriction requirement final, and Applicants continue to respectfully traverse. *Id. at Page 2.*

### **Rejections Under 35 U.S.C. § 101**

Claims 44-46 were rejected under 35 U.S.C. § 101 as purportedly reciting a use "without setting forth any steps involved in the process, result[ing] in an improper definition of a process." *Office Action at Page 3.* This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, by the foregoing amendments Applicants have cancelled Claims 44-46 without prejudice or disclaimer to Applicants filing one or more continuing applications directed to the previously-presented subject matter. Accordingly, the rejection of Claims 44-46 has been rendered moot.

**Rejections Under 35 U.S.C. § 112, Second Paragraph**

**A. Claims 44-46**

Claims 44-46 were rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite due to the claims lacking “any steps involved in the method/process.” *Office Action at Pages 2-3*. This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, by the foregoing amendments Applicants have cancelled Claims 44-46 without prejudice or disclaimer to Applicants filing one or more continuing applications directed to the previously-presented subject matter. Accordingly, the rejection of Claims 44-46 has been rendered moot.

**B. Claims 28, 39, 40-42, and 44-46**

Claims 28, 39, 40-42, and 44-46 were rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite due to the claims “not clearly set[ting] forth the metes and bounds of the patent protection desired,” due to “such as” language, due to “especially” language, due to Claim 28 further stating “injection or infusion solution,” due to Claim 42 reciting a “nitrogen atmosphere,” and due to Claim 39's percentages. *Office Action at Pages 4-6*. These rejections are respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, by the foregoing amendments Applicants have amended Claims 28, 39, 40, 41, and 42 and have cancelled Claims 44, 45, and 46.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 28, 39, 40-42, and 44-46 under 35 U.S.C. § 112, second paragraph.

**C. Claim 44**

Claim 44 was rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite due to the phrase “rescues-rescue agent.” *Office Action at Page 6*. This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, by the foregoing amendments Applicants have cancelled Claim 44 without prejudice or disclaimer to Applicants filing one or more continuing applications directed to the previously-presented subject matter. Accordingly, the rejection of Claim 44 has been rendered moot.

**Rejections Under 35 U.S.C. § 102(b) – U.S. Patent No. 5,814,635 to Buchs et al.**

Claims 28-46 were rejected under 35 U.S.C. § 102(b) as purportedly anticipated by U.S. Patent No. 5,814,635 to Buchs *et al.* (“Buchs”). According to the Examiner, Buchs “teaches a product that is identical to what is instantly claimed.” *Office Action at Page 7*. This rejection is respectfully traversed.

Applicants note that “[i]nvalidity based on ‘anticipation’ requires that the invention is not in fact new.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) (quoting *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995)). “A single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve*, 311 F.3d at 1120 (citing *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)). Put differently, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed.

Cir. 1987). Applicants assert that Buchs fails to set forth each and every element of Claims 28-46.

Buchs corresponds to European Patent No. 0 667 159, referenced at Page 3 of the instant application. As described on Page 3 of the instant application, folinic acid is a mixture of the (6RS)-diastereoisomers and is in amorphous form. In the working example of Buchs/European Patent No. 0 667 159 amorphous (6RS)-folinic acid is used.

However, it is well-known to those of ordinary skill in the art that the biologically-active form of the reduced folates has the (6S) configuration. *See, e.g.,* Juan C. Fontecilla *et al.*, 101 JOURNAL OF THE AMERICAN CHEMICAL SOCIETY 6114-6115 (1979).

Thus, the solution of Buchs/ European Patent No. 0 667 159 contains 50% of the inactive (6R) configuration. In turn, that means that the human body receiving such a composition is unnecessarily burdened, *e.g.,* by doubling the length of administration and administration of an inactive substance.

Applicants' claimed solutions are different from the solutions of Buchs/European Patent No. 0 667 159 because Applicants' claimed solutions comprise water and (6S)-sodium-folate or (6S)-potassium-folate.

Moreover, and as set forth on Page 4, Lines 15-18, of the instant application, the amorphous (6S)-folinic acid used for Applicants' claimed solutions has a stability comparable with that of crystalline (6RS)-folinic acid. *See Page 11, Lines 3-12, of the instant application.* As such, the amorphous (6S)-folinic acid is especially suited to preparing concentrated, stable solutions. *See also Page 12, Lines 8-20, of the instant application.*

Because Buchs does not teach a product identical to Applicants' claimed solutions, Applicants respectfully request withdrawal of the rejection of Claims 28-43 under 35 U.S.C. § 102(b).

**CONCLUSION**


In the event that there are any questions relating to this Amendment and Reply Pursuant to 37 C.F.R. § 1.111, or to the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 373-6000 so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4047.

Respectfully submitted,  
BINGHAM MCCUTCHEN, LLP

Date: May 4, 2009

By:

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